



U.S. Department of Justice

Michael J. Sullivan
United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

John Joseph Moakley United States Courthouse
Suite 9200
1 Courthouse Way
Boston, Massachusetts 02210

May 16, 2008

By Mail and Fax
202-778-5281

Geoffrey Hobart, Esq.
Covington & Burling
1210 Pennsylvania Avenue, NW
Washington, DC 20004-3401

Re: United States v. Biovail Pharmaceutical, Inc.

Dear Mr. Hobart:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts ("the U.S. Attorney") and your client, Biovail Pharmaceuticals, Inc. ("BPI" or "Defendant"), in the above-captioned case. The Agreement is as follows:

I. Plea

On a date no earlier than July 31, 2008 and no later than September 15, 2008, Defendant agrees to waive indictment and plead guilty pursuant to Fed R. Crim. P. 11(c)(1)(C) and 11(c)(1)(A) to the seven count Information attached as Exhibit A. The Information charges that:

- (1) BPI violated 18 U.S.C. § 371 by conspiring with others to knowingly and willfully make payments to induce another party to recommend purchasing or ordering BPI's drug Cardizem, L.A. in violation of 42 U.S.C. § 1320a-7b(b)(2)(B); and
- (2) BPI violated 42 U.S.C. § 1320a-7(b)(2)(B) by knowingly and willfully making payments to induce another party to recommend purchasing or ordering BPI's drug Cardizem, L.A.

Defendant expressly and unequivocally admits that it in fact knowingly, intentionally and willfully committed the crimes charged in Counts One through Seven of the Information, and is in fact guilty of those offenses. BPI agrees to waive venue, any applicable statutes of limitations and any legal or procedural defects in the Information.

2. Penalties

With respect to its violation of 18 U.S.C. § 371 (Count One), BPI is subject to a maximum possible fine of \$500,000, twice the gross gain derived from the offense or twice the gross loss, whichever is greatest. *See* 18 U.S.C. §§ 3571(c) and (d). The loss from this offense is \$12,357,550, and thus the maximum possible fine on Count One is \$24,715,100.

With respect to its violations of 42 U.S.C. § 1320a-7b(b)(2) (Counts Two through Seven), for each separate count, BPI is subject to a maximum possible fine of \$500,000, twice the gross gain derived from the offense or twice the gross loss, whichever is greatest. *See* 18 U.S.C. §§ 3571(c) and (d). For each of these counts, twice the gross gain or gross loss is less than \$500,000, and thus the maximum possible fine on each of Counts Two through Seven is \$500,000.

BPI may also be sentenced to a term of probation of not less than one year and not more than five years. *See* 18 U.S.C. § 3561(c)(1). BPI shall also pay a mandatory special assessment of \$400 per count of the Information, a total of \$2,800.

3. Sentencing Guidelines

The parties agree to jointly take the following positions at sentencing under the United States Sentencing Guidelines:

- a. The parties agree that the United States Sentencing Guideline Manual in effect as of November 1, 2002 should be used in determining Defendant's sentence.
- b. The parties agree that there is no basis for a departure or deviation under the factors set forth in 18 U.S.C. § 3553(a) from the sentencing range established by the United States Sentencing Guidelines.
- c. The parties agree that the Counts involve substantively the same harm, and thus group under U.S.S.G. § 3D1.2.

The U.S. Attorney's agreement that the disposition set forth below is appropriate in this case is based, in part, on Defendant's acceptance of responsibility for the offenses of conviction in this case.

The U.S. Attorney specifically may, at his sole option, be released from his commitments under this Agreement, including, but not limited to, his agreement that paragraph 4 constitutes

the appropriate disposition of this case, if at any time between his execution of this Agreement and sentencing, Defendant:

- (a) Fails to admit a complete factual basis for the plea;
- (b) Fails to truthfully admit its conduct in the offenses of conviction;
- (c) Falsely denies, or frivolously contests, relevant conduct for which Defendant is accountable under U.S.S.G. § 1B1.3;
- (d) Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which Defendant is accountable under U.S.S.G. § 1B1.3;
- (e) Engages in acts which form a basis for finding that Defendant has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1;
- (f) Attempts to withdraw its plea.

Defendant expressly understands that it may not withdraw its plea of guilty, unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5).

4. Agreed Disposition

The U.S. Attorney and Defendant agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the appropriate disposition of this case is as follows and that this fine is within the statutory maximums:

- a. A criminal fine in the amount of twenty two million two hundred forty three thousand five hundred ninety dollars (\$22,243,590), as follows:

Defendant shall pay this fine within five business days of the date of sentencing.

The parties agree that the basis for this fine is as follows:

- i. The parties agree that the base fine is \$12,357,550, which is the amount of payments to physicians and others paid by or on behalf of BPI through the PLACE program. See U.S.S.G. §§ 8C2.3, 8C2.4(b) and 2B4.1(c)(1)(A).
- ii. Pursuant to U.S.S.G. § 8C2.5, the culpability score is seven (7) as

determined as follows:

- (a) Base culpability score is five (5) pursuant to U.S.S.G. § 8C2.5(a);
 - (b) Add 3 points in that the unit of the organization within which the offense was committed had 200 or more employees, and an individual within the high level personnel of this unit participated in or condoned the offense;
 - (c) Deduct one (1) point pursuant to U.S.S.G. § 8C2.5(g)(3).
- iii. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of seven (7) is 1.4 to 2.8.
- iv. Thus, the Guideline Fine Range is \$17,300,570 to \$34,601,140.
- v. The parties agree that (1) disgorgement pursuant to U.S.S.G. §8C2.9 is not necessary, (2) there is no basis for a downward departure or deviation under the U.S.S.G.; (3) the proposed fines are within the statutory maximums pursuant to 18 U.S.C. §§ 3571(c) and (d) because the gross gain from Count One exceeded \$10,000,000; and (4) a fine within the guideline range will result in a reasonable sentence taking into consideration all of the factors set forth in 18 U.S.C. §§3553(a), 3572.
- b. Mandatory special assessments totaling \$2,800. Pursuant to 18 U.S.C. § 3013(a)(2)(B), to be imposed as \$400 per count.
- c. Restitution: Because 42 U.S.C. §1320a-7b(b)(2)(B) prohibits remuneration to induce the ordering or recommending, inter alia, of an item "for which payment may be made in whole or in part under a Federal health care program," the victims of the crimes set forth in the Information attached as Exhibit A are the federal health insurance programs. Restitution to the federal health insurance programs will be addressed by a Civil Settlement Agreement to be entered into between Defendant and the United States on or before July 31, 2008. To satisfy its restitution obligations, Defendant agrees to pay or cause to be paid \$2,404,286, plus interest at the Medicare Trust Fund Rate from May 1, 2008 to the date of payment. Defendant acknowledges that any settlement and/or release of civil liability must be approved by the Civil Division of the United States Department of Justice and the Department of Health and Human Services, Office of Inspector General.

5. Payment of Mandatory Special Assessment

Defendant agrees to pay the mandatory special assessment to the Clerk of the Court on or before the date of sentencing.

6. No Further Prosecution of Defendant

Other than the charges set forth in the Information attached as Exhibit A, the Government agrees not to bring any additional federal criminal non-tax charges against Defendant with respect to the conduct covered by the Information. This agreement is expressly contingent upon:

- a. the guilty plea of Defendant to the Information attached hereto as Exhibit A being accepted by the Court and not withdrawn or otherwise challenged; and
- b. Defendant's performance of all of its obligations as set forth in this Agreement.

If Defendant's guilty plea is not accepted by the Court or is withdrawn for any reason, or if Defendant should fail to perform any obligation under this Agreement, this declination of prosecution shall be null and void.

The United States expressly reserves the right to prosecute any individual, including but not limited to former officers, directors, employees and agents of Biovail Corporation and/or Biovail Pharmaceuticals, Inc. for the conduct set forth in the attached Information.

7. Waiver of Rights to Appeal and to Bring Collateral Challenge

Defendant is aware that it has the right to challenge its sentence and guilty plea on direct appeal. Defendant is also aware that it may, in some circumstances, be able to argue that its plea should be set aside, or its sentence set aside or reduced, in a collateral challenge such as pursuant to a motion under 28 U.S.C. § 2255.

In consideration of the concessions made by the U.S. Attorney in this Agreement, Defendant knowingly and voluntarily waives its right to appeal or collaterally challenge:

- (a) Defendant's guilty plea and any other aspect of Defendant's conviction, including, but not limited to, any rulings on pretrial suppression motions or any other pretrial dispositions of motions and issues; and
- (b) The imposition by the District Court of the sentence agreed to by the parties, as set out in paragraph 4 and, even if the Court rejects one or more positions advocated by the parties with regard to the application of the U.S. Sentencing Guidelines.

Defendant's waiver of rights to appeal and to bring collateral challenges shall not apply to appeals or challenges based on new legal principles in First Circuit or Supreme Court cases decided after the date of this Agreement which are held by the First Circuit or Supreme Court to have retroactive effect.

This Agreement does not affect the rights or obligations of the United States as set forth in 18 U.S.C. § 3742(b), and the U.S. Attorney therefore retains his appeal rights.

8. Cooperation

(a) Terms of Cooperation

Defendant shall cooperate completely and truthfully in any trial or other proceeding arising out of any federal investigation of its current and former officers, agents, employees or other persons or entities relating to the conduct set forth in the Information. Defendant shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice. Defendant shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity.

In addition, Defendant shall furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that is within the scope of any ongoing grand jury investigation, trial or other criminal proceeding in the District of Massachusetts, and that are not covered by the attorney-client privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) Defendant is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) Defendant is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) Defendant is not required to waive any privilege or claim of work product protection except to the extent set forth in the succeeding paragraph.

Defendant specifically agrees to continue to waive and/or waive any attorney-client privilege and/or work product protections regarding the legality of the PLACE program and/or the decision to enter into, implement and/or continue the PLACE program as to any such advice or communications.

Defendant acknowledges that it expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the Information and is in fact guilty of that offense. Defendant agrees that it will not make statements inconsistent with this explicit admission of guilt to the crimes charged in the Information.

9. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

10. Fed. R. Crim. P. 11(c)(1)(C) Agreement

Defendant's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). Defendant cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement. If the sentencing judge rejects this Agreement, this Agreement shall be null and void at the option of either the United States or Defendant, with the exception of paragraphs 12-13, which shall remain in effect.

11. Civil and Administrative Liability

By entering into this Agreement, the United States does not compromise any civil or administrative liability, including but not limited to any False Claims Act or tax liability which BPI may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

12. Waiver of Defenses

If this Plea Agreement or Defendant's guilty plea is not accepted by the Court for any reason, or is later withdrawn or otherwise successfully challenged by Defendant for any reason, Defendant hereby waives, and agrees it will not interpose any defense to any charges brought against it which defenses Defendant might otherwise have under any statute of limitations, the Speedy Trial Act, or the United States Constitution with respect to preindictment delay, except that Defendant may raise any such defense that Defendant may have for conduct occurring before April 1, 2003, as further described in the parties tolling agreement attached hereto as Exhibit B.

13. Withdrawal of Plea By Defendant

Should Defendant move to withdraw its guilty plea at any time, this Agreement shall be null and void at the option of the U.S. Attorney, with the exception of this paragraph. In this event, Defendant understands and agrees that the Government may pursue any and all charges that might otherwise have been brought but for this Agreement, and Defendant hereby waives, and agrees that it will not interpose, any defense to any additional charges brought against it which might otherwise have under any statute of limitations, the Speedy Trial Act, or the United States Constitution with respect to pre-indictment delay, except any such defense that Defendant may already have for conduct occurring before April 1, 2003.

14. Breach of Agreement

If the U.S. Attorney determines that Defendant has failed to comply with any provision of this Agreement, or has committed any crime following its execution of this Agreement, the U.S. Attorney may, at his sole option, be released from his commitments under this Agreement in their entirety by notifying Defendant, through counsel or otherwise, in writing. The U.S. Attorney may also pursue all remedies available to him under the law, irrespective of whether he elects to be released from his commitments under this Agreement. Further, the U.S. Attorney may pursue any and all charges which have been, or are to be, dismissed pursuant to this Agreement. Defendant recognizes that no such breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea. Defendant understands that, should it breach any provision of this agreement, the U.S. Attorney will have the right to use against Defendant before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by it, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation. In this regard, Defendant hereby waives any defense to any charges which it might otherwise have under any statute of limitations or the Speedy Trial Act.

15. Who Is Bound By Agreement

This Agreement is limited to the U.S. Attorney for the District of Massachusetts, and cannot and does not bind the Attorney General of the United States or any other federal, state or local prosecutive authorities.

16. Corporate Authorization

Defendant shall provide to the Government and the Court a copy of a resolution of the Board of Directors of Biovail Pharmaceuticals, Inc. affirming that the Board of Directors has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize Biovail Pharmaceuticals, Inc. to plead guilty to the charges specified in the Plea Agreement and (5) voted to authorize the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. A copy of the resolution is attached as Exhibit C. Defendant agrees that either a duly authorized corporate officer or a duly authorized attorney for Biovail Pharmaceuticals, Inc., at the discretion of the Court, shall appear on behalf of Biovail Pharmaceuticals, Inc. and enter the guilty plea and will also appear for the imposition of sentence.

17. Complete Agreement

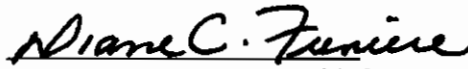
This letter and the attachments thereto (Exhibit A - the Information, Exhibit B - the Tolling Agreement and Exhibit C - the Corporate Resolution) contains the complete agreement between the parties to this Agreement relating to the disposition of this criminal case. No promises, representations or agreements have been made other than those set forth in this letter.

This Agreement supersedes prior understandings, if any, of the parties, whether written or oral, other than those set forth in the attachments hereto. This Agreement can be modified or supplemented only in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the Agreement between the U.S. Attorney and Defendant, please have Defendant sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorney Sara Bloom.

Very truly yours,

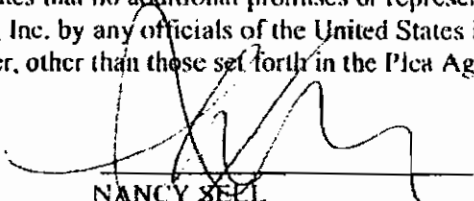
MICHAEL J. SULLIVAN
United States Attorney

By: 
DIANE C. FRENIERE, Chief
White Collar Crime Section

Acknowledgment of Plea Agreement

The Board of Directors has authorized me to execute this Plea Agreement on behalf of Biovail Pharmaceuticals, Inc. The Board has read this Plea Agreement, the attached criminal Information, the tolling agreement and the corporate authorization or has been advised of the contents thereof and has discussed them fully with Biovail Pharmaceuticals, Inc.'s attorney. The Board acknowledges that this letter fully sets forth Biovail Pharmaceuticals, Inc.'s agreement with the Government. The Board further states that no additional promises or representations have been made to Biovail Pharmaceuticals, Inc. by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement.

Dated: May 16/08


NANCY SEEL
Title: President and Secretary
Biovail Pharmaceuticals, Inc.

Dated: 5/16/08



GEOFFREY HOBART, ESQ.
Covington & Burling, LLP.
Attorney for Biovail Pharmaceuticals, Inc.

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

v.

BIOVAIL PHARMACEUTICALS, INC.

Defendants.

Criminal Number _____

VIOLATION:

18 U.S.C. § 371 - Conspiracy to Offer and Pay
Illegal Remunerations to Physicians

42 U.S.C. § 1320a-7(b)(b)(2) – Offers of
Remuneration to Physicians

INFORMATION

THE UNITED STATES ATTORNEY CHARGES THAT:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

1. Defendant **BIOVAIL PHARMACEUTICAL, INC. ("BPI")**, a Delaware corporation, had corporate headquarters in Morrisville, North Carolina.

The Drug Cardizem, L.A.

2. In January 2001, **BPI** acquired the Cardizem line of drugs from another company for \$409.5 million dollars.
3. Cardizem is the brand name of a drug known as diltiazem, which is a heart medication used to control high blood pressure.
4. In or before 2003, the patent ran out on Cardizem, the then brand name version of diltiazem, and the drug faced generic competition.

5. In late 2002 and early 2003, **BPI** was preparing to introduce the product Cardizem, L.A. (CLA) to the market. Cardizem, L.A. was **BPI's** proprietary name for a new 24 hour time release, or long acting (L.A.), formulation of the brand name drug Cardizem.
6. **BPI** began selling Cardizem, L.A. on or about March 23, 2003. At that time, the generic version of Cardizem cost about one third less than the new drug, Cardizem, L.A.

The PLACE Program

7. As part of their promotion of Cardizem, L.A., beginning in March 2003, **BPI** implemented a program known as the PLACE (Proving Long Acting Through Experience) program.
8. The PLACE program paid physicians and other prescribers up to \$1,000 for enrolling between 11-15 patients in the program, causing patients to fill prescriptions for Cardizem, L.A. These included prescriptions that were paid for by Medicaid.
9. The first phase of the PLACE program required the prescribing medical professionals (e.g. physicians, nurse practitioners, physician's assistants) to enroll in the program by signing a business reply card by which they agreed to participate, and by completing a 2 page, 10 multiple choice questionnaire. This questionnaire was not expected to take, and did not usually take, the prescribing professional more than 10 minutes to complete.
10. Under this initial part of the program, the prescribing medical professionals were paid \$250 if they (a) signed the business reply card and thus agreed to participate in the program and write Cardizem, L.A. prescriptions for their patients, and (b) completed this brief questionnaire.

11. A payment of \$250 for 10 to 15 minutes of these medical professionals' time exceeded the reasonable fair market value of their time.
12. In addition, if the business reply card was signed and the questionnaire completed and returned, an office manager or assistant received \$50.00. In some cases, these assistants simply put the materials in an envelope. In other cases, the assistants did nothing at this stage.
13. The payments of \$50 to these office assistants exceeded the reasonable fair market value of the assistants' actual time spent.
14. The second phase of the PLACE program provided that if the medical prescriber returned the final questionnaire, they would be paid, in addition to the initial \$250 payment, as follows:
 - (1) an additional \$250 if they enrolled between 1 and 5 patients;
 - (2) an additional \$500 if they enrolled between 6 and 10 patients; and
 - (3) an additional \$750 if they enrolled between 11 and 15 patients.
15. These payments of \$250-\$750 exceeded the reasonable fair market value of the medical prescribers' time necessary to enroll these patients and complete the final questionnaire.
16. In addition, if the final questionnaire was returned, the office assistant also received an additional \$100.00. This payment also exceeded the fair market value of the office assistants' time necessary to complete the program.
17. To enroll a patient, the physician or other medicine prescriber was required to write a 30 day prescription for the patient and the patient had to fill the prescription. BPI provided a coupon or voucher, however, so that first thirty days of the drug would be free.

18. The physicians and other medicine prescribers were told that in order to receive the payment they also had to track the patients experience on Cardizem, L.A. for three regularly scheduled visits. These visits were nothing more than the routine visits and required no additional work for the prescriber.
19. **BPI** did not design or implement the PLACE program in a way calculated to provide new or meaningful scientific data about whether Cardizem, L.A. worked better than other available drugs.
20. **BPI** employees responsible for the PLACE program reported regularly on the number of prescriptions generated by the PLACE program and congratulated those involved for their success in using the PLACE program to generate prescriptions for Cardizem, L.A.
21. **BPI** paid and caused full payments to be made to medical prescribers and office assistants even if the information provided in the final study questionnaire was incomplete and/or not usable.
22. According to the final study report, nearly 64 percent of the final study questionnaires were not complete or contained inconsistent data.
23. The senior management of **BPI** and **BPI's** parent company communicated to the sales force that a successful launch of Cardizem, L.A. was critical to **BPI's** success and growth as a company, as well as to their own financial well-being. On February 28, 2003, a **BPI** parent company Vice President sent an email to the sales force with respect to the launch of Cardizem, L.A that stated:

We have to deliver growth to Wall Street and everyone knows exactly what is expected from us. If we ever don't deliver, my net worth will shrink dramatically. I will suffer tremendously if this were to happen . . . We have made a huge

upfront commitment and now we expect you (the reps) to make a commitment in return.

24. **BPI** and its parent company management also congratulated the sales team on its success in using the **PLACE** program to drive prescriptions for Cardizem, L.A.

25. Thus, on or about April 11, 2003, the **BPI** Product Manager in charge of the **PLACE** program sent an email to all district sales managers that stated:

Congratulations on doing an incredible job with the **PLACE** Program. The prescription generation has been phenomenal – Currently, we have 10,505RXs!!

26. Similarly, on June 23, 2003, this **BPI** Product Manager sent another email, including higher level sales and marketing managers, as follows:

To date, a total of 89,092 Rxs have been recorded for Cardizem LA, as of June 6th 2003. Congratulations once again on all the success the **PLACE** Program is having in driving prescriptions and market share!!

27. In addition, on April 5, 2003, the CEO of **BPI's** parent company responded to a report of increasing Cardizem, L.A. prescriptions from the **PLACE** program with the following:

This is a GREAT start. Now, who would care to venture a guess (don't we call them forecasts?) on what conversion we can expect to paying customers. I would really like to know what you think. Thanks and nice work.

28. Likewise, on April 8, 2003, the CEO of **BPI's** parent company responded to reports of 8356 faxed in prescription forms with "I have to tell you, I have NEVER seen this type of response!! CONGRATS!!!"

29. In preparing to launch Cardizem, L.A., **BPI** also contracted with R-Corp. to acquire a additional contracted sales representatives to promote Cardizem, L.A. at the time of its launch. Under the agreement, R-Corp. sales representatives were hired to help **BPI** sales representatives promote Cardizem, L.A. at its launch.

30. Prior to the launch of Cardizem, L.A., R-Corp. representatives raised a concern about whether the PLACE program complied with all laws, and specifically the Anti-Kickback laws and indicated that R-Corp. was unwilling to proceed without assurances that the program complied with the Anti-Kickback Act.
31. On or about March 21, 2003, an attorney for R-Corp. spoke with counsel for BPI's parent company and informed the counsel for BPI's parent company about R-Corp.'s internal guidelines regarding the Anti-Kickback Act. These included the following:
- The purpose of the study cannot be to induce physicians to prescribe the product . . .
- The compensation cannot take into account the volume or value of any referrals or business generated between the parties . . .
- The recruitment of investigators needs to be aimed at practitioners that are experts in the field or leading researchers.
- Recruitment of investigators is not to be aimed at high prescribers.
 . . Participation in the research and any payments cannot be made contingent upon a practitioner prescribing a Reliant product.
 [Emphasis in original]

The Medicaid Program

32. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*, established a program to enable the states to furnish medical assistance to certain categories of persons whose income and resources were insufficient to meet the costs of necessary medical services. Commonly called Medicaid, the program was administered by the states, but was funded jointly by the federal and state governments.
33. To participate in the Medicaid program, a state was required to develop a plan that was approved by the Secretary of Health and Human Services as meeting federal

requirements. The state paid qualified providers for furnishing necessary services covered by the state plan to individuals who were eligible for medical assistance. The federal government contributed a portion of the costs that each participating state incurred in purchasing items and services from qualified providers on behalf of eligible persons. The state bore the remainder of the costs. At all times relevant hereto, Massachusetts was among the states that had Medicaid programs receiving federal funding.

34. Medicaid programs, including that in Massachusetts, were “federal health care programs” within the meaning of 18 U.S.C. § 24, in that they were public plans affecting commerce under which medical benefits, items and services were provided to individuals under the plans.
35. The federal government contributed to the costs of prescription drugs for persons who were Medicaid beneficiaries, including but not limited to persons receiving prescriptions for blood pressure treatment, such as Cardizem, L.A.
36. As discussed in this Information, prescribers D, E, G, R, S and W were each medical providers in Massachusetts who provided care and treatment for Medicaid-eligible patients for high blood pressure. Each of these prescribers prescribed Cardizem, L.A. for one or more patients who were Medicaid program beneficiaries in 2003. At all times relevant to this Information, the Medicaid program in Massachusetts reimbursed the Cardizem, L.A. prescriptions for the physicians' Medicaid eligible patients.
37. At all times relevant to this Information, federal law provided that it was illegal to knowingly and willfully offer or pay any remuneration (including any kickback, bribe or

rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person *to induce* such person to *order*, or arrange for or *recommend purchasing*, any item for which payment may be made in whole or in part under a Federal health care program.

38. **BPI** employees knew that Cardizem, L.A. prescriptions, including those induced through the PLACE program, would include prescriptions for Medicaid patients.
39. In 2003, Medicaid paid in excess of \$3 million in reimbursement for prescriptions for Cardizem, L.A nationwide.

**COUNT ONE
(CONSPIRACY - 18 U.S.C. § 371)**

The Conspiracy

40. The allegations set forth in Paragraphs 1- 39 are herein realleged and incorporated by reference.
41. Commencing on or before August 2002, and continuing thereafter until in or about at least December 2003, the exact dates being unknown to the Grand Jury, in the District of Massachusetts and elsewhere, defendants

BIOVAIL PHARMACEUTICALS INC.,

and others known and unknown to the Grand Jury, did knowingly and willfully combine, conspire, and agree to commit an offense against the United States, to wit, 42 U.S.C. § 1320a-7b(b)(2)(A), by knowingly and willfully offering and paying remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to physicians to induce them to prescribe Cardizem, L.A. for individuals, including Medicaid patients, for which payments were made in whole and in part under Medicaid and other Federal health care insurance programs.

Purpose of the Conspiracy

42. The purpose of the conspiracy was to target medical prescribers who were potential high prescribers of Cardizem, L.A. and to offer them payments and to pay them to induce them to prescribe Cardizem, L.A. for their patients, including their Medicaid patients.

Manner and Means of the Conspiracy

It was part of the conspiracy that :

43. From March 2003 through at least December 2003, **BPI** implemented the PLACE program to induce medical prescribers to prescribe Cardizem, L.A. for their patients.
44. From March 2003 through at least December 2003, **BPI** presented the PLACE program to medical prescribers and others as a scientific study of the performance of Cardizem, L.A., when the program was actually designed to induce prescribers to prescribe the product for their patients by paying prescribers up to \$1,000.
45. From November 2002 through at least on or about March 2003, **BPI** confirmed their objectives for the Cardizem, L.A. program to include the following:
 - (1) Accelerate uptake among high prescribing PCPs;
 - (2) Engage physicians in evaluation of Cardizem [L.A.]; and
 - (3) Provide sales reps with an opportunity to reinforce/build relationships with key prescribers.
46. From March 2003 through at least December 2003, **BPI** paid the participants in the PLACE program more than the fair market value of their time in order to induce them to try Cardizem, L.A. on their patients.
47. From in or about October 2002 through on or about February 2003, **BPI** increased the payments to the physicians from the originally proposed honorarium of \$100 (or a medically relevant item) to \$300, then \$500 and then \$1,000 per prescriber.
48. In furtherance of the conspiracy, **BPI** paid the physicians up to \$1,000 for their participation, without seeking attorney advice regarding the legality of the payments, even though **BPI** was advised by Q-Corp., the company helping **BPI** to help design and implement the PLACE program, that **BPI** would have to consult its own attorneys as to

the appropriateness and permissibility of increasing the payment to such a high honorarium.

49. From in or about March 2003 through at least July 2003, **BPI** created 25,000 PLACE kits and targeted approximately 17,000 prescribers for participation in the program and provided these target lists to their sales representatives.
50. From in or about March 2003 through at least July 2003, **BPI** targeted prescribers based upon their projected potential and likelihood of prescribing Cardizem, L.A.
51. From in or about March 2003 through at least May 2003, **BPI** falsely assured other participants, and specifically representatives of R-Corp., that the PLACE program had been reviewed by attorneys for compliance with the Anti-Kickback statutes as well as other laws, when in fact no such review had been done.
52. In or about March 2003, a Vice President of **BPI**'s parent company dismissed R-Corp's concern about compliance with the Anti-Kickback Act as whining, indicated he did not really care what R-Corp had to say about it, and insisted that the program had to proceed to meet **BPI**'s objectives.
53. In or about March 2003, this Vice President, when questioned further about how to deal with the objections concerning the program's potential lack of compliance with the Anti-Kickback Act, caused the program to go forward, concluding: "This is a formality anyway. The program has to proceed."
54. On or about April 10, 2003, **BPI** and a Vice President of its parent corporation signed a letter to R-Corp. in which **BPI** confirmed to R-Corp. the following:

You have indicated, and assured us, that Biovail and [Q-Corp.] have carefully reviewed the program from an anti-kickback perspective . . . and firmly believe

that the program does not present an unreasonable risk of enforcement action. Further, you have indicated that the program has been reviewed by expert counsel well versed in these regulatory and enforcement matters and that counsel has confirmed your position. It is on the basis of your assurances, therefore, that we have agreed to enter an agreement directly with [Q-Corp]. to implement the Project.

You have agreed to indemnify and hold R-Corp. . . harmless from any losses . . . arising from or relating to the Project including any losses relating to any governmental or enforcement actions relating to the same.

55. On or about April 10, 2003, **BPI** executed this letter to persuade R-Corp. to go forward with the PLACE program, even though **BPI** had not obtained any review of the PLACE program's compliance with the Anti-Kickback Act, much less an expert counsel review of the PLACE program from an anti-kickback perspective.
56. From in or about March 2003 through in or about July 2003, **BPI** made the false representation that they had a legal advice as to the lawfulness of the PLACE program from an anti-kickback perspective in order to persuade R-Corp. to proceed with the program.
57. From in or about April 2003 through at least December 2003, **BPI** caused health insurers, including federal health care programs such as Medicaid, to pay for Cardizem, L.A. prescriptions generated by the PLACE program.

Overt Acts

58. In furtherance of the conspiracy, and to effect its objects, **BPI** and other co-conspirators known and unknown to the Grand Jury, committed numerous overt acts, including, but not omitted to, the following:

59. On various dates between March 2003 and in or about July 2003, **BPI** enrolled and caused to be enrolled approximately 15,000 prescribers in the PLACE program, including the six prescribers identified in the chart below.
60. On various dates between March 2003 and in or about September 2003, **BPI** caused approximately 5,000 prescribers, including the prescribers identified in the chart below, to be paid \$250 for filling out the initial questionnaire.
61. On or about the dates set forth below and thereafter, **BPI** caused approximately 10,000 prescribers, including the prescribers identified in the chart below, to be paid and additional \$750 for enrolling 11-15 patients.
62. In 2003, each of the prescribers identified in the chart below prescribed Cardizem, L.A. for patients for whom the prescriptions were reimbursed by Medicaid:

<u>Prescriber</u>	<u>Enrollment Date On or About</u>	<u>\$750 Payment Date On or About</u>
Prescriber D Dartmouth MA	May 6, 2003	November 5, 2003
Prescriber E Braintree, MA	April 9, 2003	November 5, 2003
Prescriber G Bridgewater, MA	June 2, 2003	November 5, 2003
Prescriber R Springfield, MA	April 28, 2003	November 5, 2003
Prescriber S Agawam, MA	April 29, 2003	November 5, 2003
Prescriber W Long Meadow, MA	April 14, 2003	November 5, 2003

All in violation of Title 18, United States Code, Section 371.

**COUNTS TWO - SEVEN
(OFFER OF REMUNERATION TO PHYSICIANS)
(42 U.S.C. § 1320a-7(b)(2)(A))**

63. Paragraphs 1-62 are realleged and incorporated as if fully set forth herein.
64. From on or about March 21, 2003 through January 1, 2005, in the District of Massachusetts and elsewhere, defendant

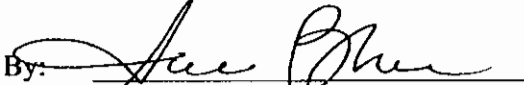
BIOVAIL PHARMACEUTICALS, INC.,

did knowingly and willfully cause to be offered remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to the physicians and other medical prescribers listed below to induce those prescribing medical professionals to prescribe Cardizem, L.A. for their patients, including their Medicaid patients, for which payments for prescriptions beyond the first month of free drug, would be made in whole and in part under state Medicaid programs, as follows:

<u>Count</u>	<u>Date of Offer</u> (On or About)	<u>Medical Prescriber</u>
2	May 6, 2003	Medical Prescriber D
3	April 9, 2003	Medical Prescriber E
4.	June 2, 2003	Medical Prescriber G
5	April 28, 2003	Medical Prescriber R
6	April 29, 2003	Medical Prescriber S
7	April 14, 2003	Medical Prescriber W

All in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(A).

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By: 
SARA MIRON BLOOM
ASSISTANT UNITED STATES ATTORNEY

Date: 5/16/08

EXHIBIT B



U.S. Department of Justice

*United States Attorney
District of Massachusetts*

Main Reception: (617) 748-3100

*(United States Courthouse, Suite 9200)
1 Courthouse Way
Boston, Massachusetts 02210*

April 2, 2008

By TELEFAX
202-778 5281

Geoffrey Hobart, Esq.
Covington & Burling
1210 Pennsylvania Avenue, NW
Washington, DC 20004-3401

Re: Biovail: Tolling Agreement on Statute of Limitations

Dear Mr. Hobart:

This letter confirms and sets forth an agreement between the Office of the United States Attorney for the District of Massachusetts and your clients, Biovail Corporation, Biovail Pharmaceuticals, Inc. and all parents, subsidiaries, successors and assigns (hereinafter "Biovail"). The terms of the agreement are as follows:

1. As you are aware, this Office is presently conducting a joint criminal and civil investigation of your client, Biovail, and its officers, employees and agents. That conduct includes, without limitation, allegations that Biovail and certain of its officers, employees and agents, may have violated various federal criminal statutes, including but not limited to 18 U.S.C. §371 (conspiracy to defraud the United States), 18 U.S.C. § 1341 and 1343 (mail and wire fraud), 342 U.S.C. §1320(a)-7(b) (criminal penalties for acts involving the Medicare and State health care programs), certain civil statutes including but not limited to 31 U.S.C. § 3729 (civil False Claims Act); and certain administrative statutes such as 42 U.S.C. § 1320a-7 (exclusion) and 42 U.S.C. § 1320a-7a (civil monetary penalties), in connection with Biovail's activities in connection with the distribution, sale, marketing, approval, and promotion of the drug Cardizem, L.A.
2. In the course of our discussions, this Office has expressed its intention to afford you and your client the further opportunity to provide information to this Office which you deem relevant to matters relating to that investigation. In response, you have advised us that you intend to provide certain information to this Office, and that you wish such information be considered

prior to a prosecution decision concerning potential criminal charges resulting from that investigation. You have requested further time to prepare any materials and gather information for presentation to this Office, and to consider and evaluate further information as may be provided by this Office. As a result, this Office and your client have agreed, as more fully set forth below, to toll the applicable statutes of limitations for the offenses described in paragraph one for the time period April 2, 2008 through October 30, 2008 for that conduct described in paragraph one.

3. This Office and your client, Biovail, hereby agree that your client will not at any time interpose a statute of limitations defense or any constitutional claim based upon pre-indictment delay to any indictment or count thereof, or to any civil complaint or count thereof, or to any administrative action, which charges or alleges that your client committed any federal offense or violation related to the conduct described in paragraph one, that includes the time period April 2, 2008 to October 30, 2008 in the calculation of the limitations period. Nothing herein shall affect, or be construed as any waiver of, any applicable statute of limitations defenses that Biovail may have with respect to the time period prior to and including April 1, 2008, and your client expressly reserves its right to raise any such defense. Any provisions of this agreement notwithstanding, except to the extent that your client has waived certain statute of limitation defenses in any waiver agreement(s) with other United States Attorney's Offices or the Department of Justice, which agreement(s) remain in effect.

4. Your client, Biovail, enters into this agreement knowingly and voluntarily. Biovail acknowledges that the statute of limitations and United States Constitution regarding prejudicial pre-indictment delay confers benefits on it, and it is not required to waive those benefits, and that Biovail is doing so after consulting with you because Biovail believes it is in its best interest to do so. Biovail also acknowledges its understanding that it may be charged with the foregoing criminal offenses and civil and administrative violations and/or any other offenses or violations at any time prior to, and including October 30, 2008. Biovail further acknowledges its understanding that it may be charged with any offenses or violations not specifically described above, at any time during the relevant statute of limitations period.

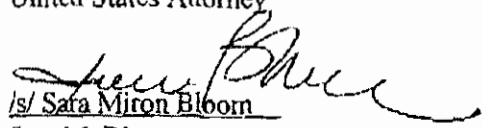
5. This agreement relates only to the allegations described in paragraph one above and any charges or claims based on those allegations. This writing contains the entire agreement between this Office and your client concerning the statute of limitations with respect to these matters and can be modified or supplemented only by means of a writing signed by this Office and your client.

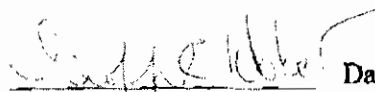
If your client is willing to enter into this agreement on the terms set forth above, Biovail should indicate the same by signing on the spaces provided below.

Very truly yours,

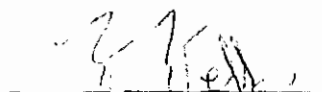
MICHAEL J. SULLIVAN
United States Attorney

By:


/s/ Sara Miron Bloom
Sara M. Bloom
Assistant U.S. Attorney


Geoffrey Hobart
Covington & Burling
Attorney for Biovail Corporation and Biovail Pharmaceuticals, Inc.

Dated: 5/13/08


William Wells
Chief Executive Officer
Biovail Corporation

Dated: 5/14/08

Wendy Kelly
Director and Authorized Representative
Biovail Pharmaceuticals, Inc.


Dated

If your client is willing to enter into this agreement on the terms set forth above, Biovail should indicate the same by signing on the spaces provided below.

Very truly yours,

MICHAEL J. SULLIVAN
United States Attorney

By:


/s/ Sara Miron Bloom
Sara M. Bloom
Assistant U.S. Attorney


Dated:

Geoffrey Hobart
Covington & Burling
Attorney for Biovail Corporation and Biovail Pharmaceuticals, Inc

Dated:

William Wells
Chief Executive Officer
Biovail Corporation

Dated



Wendy Kelly
Director and Authorized Representative
Biovail Pharmaceuticals, Inc.

EXHIBIT C

May 16, 2008

**UNANIMOUS WRITTEN CONSENT OF
THE DIRECTORS OF
BIOVAIL PHARMACEUTICALS, INC.**

THE UNDERSIGNED, being the sole director of Biovail Pharmaceuticals, Inc., a Delaware corporation (the "Corporation"), does hereby give her written consent, in accordance with Section 141(f) of the General Corporation Law of the State of Delaware, in lieu of action at a meeting of the board of directors of the Corporation, to the adoption of the following resolutions:

WHEREAS, the United States Attorney for the District of Massachusetts has been conducting an investigation into the Corporation's conduct alleging that the Corporation offered remuneration to physicians to recommend the purchase one of the Corporation's drug products (the "Investigation");

WHEREAS, the Corporation's legal counsel has been negotiating a resolution of the Investigation; and

WHEREAS, the Corporation's legal counsel has reported to the board the terms and conditions of a proposed resolution of the Investigation;

NOW, THEREFORE, IT IS:

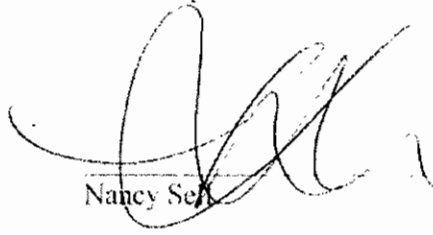
RESOLVED, that the Corporation is hereby authorized to enter into the Plea Agreement dated May 16, 2008, between the United States Attorney for the District of Massachusetts and the Corporation (the "Agreement");

FURTHER RESOLVED, that Nancy Sell, President & Secretary, is hereby authorized and directed in the name and on behalf of the Corporation to take all actions and deliver any agreements, certificates and documents and instruments with respect to or contemplated by the Agreement and matters set forth above, including, without limitation, the payment of all amounts, fees, costs and other expenses necessary or appropriate to effectuate the purpose and intent of the foregoing resolutions and to effectuate and implement the settlements contemplated hereby;

FURTHER RESOLVED, that any actions taken by the officers of the Corporation prior to the adoption of these resolutions that are within the authority conferred hereby are hereby fully ratified, confirmed and approved as the act and deed of the Corporation; and

FURTHER RESOLVED, that this Written Consent be filed with the minutes of the Board of Directors of the Corporation.

IN WITNESS WHEREOF, the undersigned has set her hand as of the day and year first above written.



Nancy Seft